COMPOSITIONS AND METHODS FOR DETERMINING IMMUNE STATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 12/313,086, filed on Nov. 17, 2008, which claims the benefit of U.S. Provisional Patent Application Ser. No. 61/003,397, filed on Nov. 16, 2007, both of which are incorporated herein by reference in their entirety.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] The present invention was made in conjunction with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), under Contract Number W81XWH-05-2-0077. The U.S. Government has a paid-up license in this invention and the right in limited circumstances to require the patent owner to license others on reasonable terms as provided for by the terms of Contract Number W81XWH-05-2-0077 awarded by the United States Army Medical Research Institute of Infectious Diseases.

THE NAMES OF PARTIES TO A JOINT RESEARCH AGREEMENT

[0003] N/A

INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC

[0004] N/A

BACKGROUND OF THE INVENTION

[0005] Historically, countries have tried to limit the spread of pathogenic agents. Many attempts at this have been made over centuries. In many instances, such measures have involved quarantining individuals known of having or suspecting of having the pathogenic agent. However, one early issue in controlling the spread of pathogenic agents is the identification of those individuals who carry the agent. In some aspects, the invention is intended to provide efficient means for the identification of these individuals.

[0006] One recent report discusses bacterial antigen microarray technology produced by covalent coupling of oligosaccharide antigens specific for several organisms. These microarrays are then used to identify antigen specific antibodies in sera of individuals. (Blixt, et al., *Glycoconj. J.* 25:27-36, 2008, Epub Jun. 9, 2007).

[0007] In other aspects, the invention provides means for identifying molecules of pathogenic agents, as well as regions of such molecules, against which individuals produce antibodies (e.g., protective antibodies).

SUMMARY OF THE INVENTION

[0008] The invention provides compositions and methods for identifying molecules (e.g., antibodies) in samples (e.g., whole, blood, serum, cerebrospinal fluid, ascites, saliva, etc.) that bind to molecules (e.g., lipids, carbohydrates, proteins, etc.) associated with pathogenic agents (e.g., infectious agents). In some aspects, the invention may be used to identify individuals (e.g., humans, non-human animals (e.g., cows, chickens, ducks, pigs, mice, etc.), etc.) that have been exposed to one or more pathogenic agent (also referred to as a "pathogen") or have generated antibodies (e.g., protective antibodies) in response to one or more pathogenic agent. In other aspects, the invention is directed to the identification of molecules of one or more pathogenic agent that may be used to generate immune responses (e.g., protective immune responses) in other individuals.

[0009] In various aspects, the invention includes collections of molecules. Molecules in such collections may be identical to one or more molecule from one or more pathogenic agent and/or may share structural similarity to one or more molecule from one or pathogenic agent (e.g., one or more pathogenic agent for which a vaccine exists). In many instances, when a molecule of such collections shares structural similarity to one or more molecule from one or pathogenic agent, the similarity will be such that the molecule of the collection either binds to antibodies (e.g., polyclonal or monoclonal) that bind to at least one of the one or more molecule the pathogenic agent.

[0010] In specific aspects, the invention includes compositions that comprise one or more (e.g., at least two, at least three, at least four, at least five, at least ten, at least fifteen, at least twenty, at least thirty, at least fifty, at least one hundred, at least three hundred, at least seven hundred, at least one thousand five hundred, at least four thousand, etc.; from about two to about five thousand, from about twenty to about five thousand, from about fifty to about five thousand, from about one hundred to about five thousand, from about two hundred to about five thousand, from about five hundred to about five thousand, from about fifty to about five thousand, from about fifty to about three thousand, from about fifty to about one thousand, from about twenty to about five thousand, from about twenty to about one thousand, etc.) protein (or other molecule such as a carbohydrate, DNA or RNA), each of which shares at least some structural features (e.g., similarity) with one or more molecule derived from one or more pathogenic agent. As examples, molecules used in the practice of the invention may be (1) located in separate locations on a solid support, located in separate containers (e.g., the individual wells of a microtiter plate, and/or (3) mixed together (e.g., two or more such as two to ten, three to ten four to ten, etc.) and contained in the same location and/or container.

[0011] When the molecule is a protein, molecules of the composition will typically share at least ten, at least twenty, at least thirty, at least fifty, at least seventy, at least one hundred (e.g., from about ten to about eighty, from about ten to about ninety, from about fifteen to about eighty, from about twenty to about eighty, from about thirty to about eighty, from about ten to about fifty, from about ten to about thirty, from about twenty to about fifty, etc.), etc. amino acids of sequence identity or similarity to a particular protein of a pathogenic agent. Of course, the full-length protein of the pathogenic agent may be used, as well as subportions of at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, at least 85%, at least 90%, at least 95%, etc. of the full-length protein.

[0012] Any number of different pathogenic agents may be used in the practice of the invention. For example, the pathogenic agents may be one or more agent of a class selected from the group consisting of a protozoan, a virus, a viroid, a bacterium, and a parasite (e.g., a multicellular parasite, such as a worm).

[0013] Any number of different solid supports may be used in the practice of the invention. Examples of solid support comprises include those composed of one or more material